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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/810,939	03/16/2001	Mary Capelli-Schellpfeffer	3066.1000-001	7242

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EXAMINER	
GHALI, ISIS A D	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 05/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/810,939	CAPELLI-SCHELLPFEFFER, MARY	
	Examiner	Art Unit	
	Isis Ghali	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 February 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *80,89,103,109 and 111-118* is/are pending in the application.

4a) Of the above claim(s) *112-118* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *80,89,103,109 and 111* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The receipt is acknowledged of applicant's request for extension of time, request for RCE and amendment, all filed 11/07/2005; declaration filed 01/05/2006; and election filed 02/23/2006.

Claims 1-79, 81-88, 90-102, 104-108, and 110 have been cancelled.

Claims 111-118 have been added.

Claims 80, 89, 103, 109 and 111-118 are pending.

Election/Restrictions

1. Claim 103 is currently amended to recite topical composition as required by the method claim 80, therefore, claims 103 and 111 directed to kit comprising topical composition will be examined with the method claims 80, 89 and 109. Therefore the election between Group I and Group II has been **withdrawn**.

2. Applicant's election of species (a), claims 80, 89, 103, 109, and 111, in the reply filed on 2/23/2006 is acknowledged. Because applicant did not distinctly and

specifically point out the supposed errors in the restriction requirement, the election has been treated as an election **without** traverse (MPEP § 818.03(a)).

3. Claims 112-118 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species (b), there being no allowable generic or linking claim. Election is considered **without** traverse as set forth.

Claims 80, 89, 103, 109, and 111 are included in the prosecution.

Continued Examination Under 37 CFR 1.114

4. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/07/2005 has been entered.

Specification

5. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 80, 89, 103, 109 and 111 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification does not describe the claimed derivatives of salicylic acid and acetylsalicylic acid. The specification does not describe the aryl, substituted or unsubstituted aralkyl, allyl, and substituted or unsubstituted, linear, branched, or cyclic alkyl esters of salicylic acid; neither describes aryl, substituted or unsubstituted aralkyl, allyl, and substituted or unsubstituted, linear, branched, or cyclic alkyl esters of acetylsalicylic acid. The specification does not describe reasonable number of pharmaceutically acceptable salts of all the claimed non-steroidal anti-inflammatory drugs (NSAID), neither reasonable number of the possible combinations of the claimed NSAID.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 80, 89, 103, 109, and 111 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 08-259465 ('465).

JP '465 teaches external preparation containing NSAID including indomethacin and flufenamic acid, carrier including gel (instantly claimed in claims 89 and 109 as thermal insulating material) and polyethylene glycol (abstract; paragraphs 0008, 0019). The reference teaches that the external preparation is useful to treat skin diseases such as keloid and hypertrophic scar and does not have adverse effects (paragraph 0022). The NSAID is present in the preparation in an amount of 1-60% (abstract).

JP '465 suggests the treatment of keloid and hypertrophic scar using NSAID, however, it does not teach the claimed causes of the scar, or the kit. The causes of the scar do not impart patentability to the claimed method because it is expected that NSAID will have the same effect on any scar regardless to the cause. The kit is considered a composition, and the separation of the NSAID and the carrier within a kit is within the skill of an artisan versed in the pharmaceutical art in order to increase the shelf life of the NSAID.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to use the external preparation disclosed by the JP '465 to treat keloid and hypertrophic scar caused by any causes such as burn or surgical operation, motivated by the teaching of JP '465 that external preparation comprising NSAID is

useful to treat skin diseases such as keloid and hypertrophic scar and does not have adverse effects, with reasonable expectation of treating any scar tissue by topical application of NSAID.

10. Claims 80, 89, 103, 109, 111 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,652,856 ('856) in view of US 5,552,162 ('162).

US '856 teaches method for treating fibrosis including dermal fibrosis such as keloid and hypertrophic skin caused by surgical wounds and traumatic laceration by using composition comprising the NSAID sulfasalazine in a glycol carrier (abstract; col.6, lines 15-16, 30-36; col.11, lines 66-67; col.12, lines 17-20, 27).

US '856 suggests the treatment of keloid and hypertrophic scar using NSAID, however, it does not teach the claimed amount of NSAID, or the kit. US '856 does not teach thermal insulating agent.

The claimed amount of NSAID does not impart patentability to the claims, absent evidence to the contrary. The kit is considered a composition, and the separation of the NSAID and the carrier within a kit is within the skill of an artisan versed in the pharmaceutical art in order to increase the shelf life of the NSAID.

US '162 teaches a method for improving the size and appearance of the scar associated with keloid or hypertrophic wound healing disorder by covering the scar with thermal insulating material and active agent (abstract). The thermal insulating materials includes hydrogel and gel (col.9, lines 10-12, 27). The thermal insulating material elevates the surface temperature of the scar and consequently stimulates the

collagenase activity and improves the size and the appearance of the scar (col.6, lines 1-32).

Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide the method for improving the keloid and scar by administering a composition comprising NSAID as disclosed by US '856, and add the thermal insulating hydrogel disclosed by US '162, motivated by the teaching of US '162 that the thermal insulating material elevates the surface temperature of the scar and consequently stimulates the collagenase activity and improves the size and the appearance of the scar as desired by the applicant, with reasonable expectation of having a composition comprising the aspirin and hydrogel that improves the size and the appearance of the scar with success.

11. Claims 80 and 103 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,521,271 ('271) with the effective filing date of August 16, 1999.

US '271 teaches method of improving skin conditions such as scar by, administration of a composition that can be in the form of topical composition comprising 1-20% of hydroxyl acid such as salicylic acid and a carrier (abstract; col.3, lines 13-15, 35-37, 39-40; col.7, lines 15-23, 40; col.8, lines 19-21, 26, 30, 38-50). The hydroxyl acids are delivered topically to the skin in doses that are highly effective without causing significant skin irritation (col.3, lines 1-3).

US '271 suggests the treatment of scar by topical application of the composition comprising NSAID (col.9, lines 64-66), however, it does not teach the claimed causes of

the scar, or the kit. The causes of the scar do not impart patentability to the claimed method because it is expected that NSAID will have the same effect on any scar regardless to the cause. The kit is considered a composition, and the separation of the NSAID and the carrier within a kit is within the skill of an artisan versed in the pharmaceutical art in order to increase the shelf life of the NSAID.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to use the topical composition disclosed by the US '271 to treat scar caused by any causes such as burn or surgical operation, motivated by the teaching of US '271 that the topical composition comprising NSAID is delivered in a dose that is highly effective to treat scar without causing significant skin irritation, with reasonable expectation of treating any scar tissue by topical application of NSAID.

12. Claims 80, 89,103 and 109 and 111 are rejected under 35 U.S.C. 103(a) as being unpatentable over US '271 in view of US 5,552,162 ('162).

The teaching of US '271 are discussed above, however, US '271 does not teach the thermal insulating material.

US '162 teaches a method for improving the size and appearance of the scar associated with keloid or hypertrophic wound healing disorder by covering the scar with thermal insulating material and active agent (abstract). The thermal insulating materials includes hydrogel and gel (col.9, lines 10-12, 27). The thermal insulating material elevates the surface temperature of the scar and consequently stimulates the

collagenase activity and improves the size and the appearance of the scar (col.6, lines 1-32).

Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide the method for improving the scar by administering a composition comprising non-steroidal anti-inflammatory agent as disclosed by US '271, and add the thermal insulating hydrogel disclosed by US '162, motivated by the teaching of US '162 that the thermal insulating material elevates the surface temperature of the scar and consequently stimulates the collagenase activity and improves the size and the appearance of the scar as desired by the applicant, with reasonable expectation of having a composition comprising the aspirin and hydrogel that improves the size and the appearance of the scar with success.

13. Claims 103 and 111 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,244,948 ('948).

Claim 103 is directed to composition, and the future intended use of the does not impart patentable weight to composition claims.

US '948 teaches topical composition comprising esters of acetylsalicylic acid in amount of 1-10%, carrier comprising water and polyethylene glycol (abstract; col.1, lines 45-50; col.2, lines 20-23, 33-35). The composition comprises gel (col.2, line 48).

US '948 does not teach the kit. The kit is a composition, and the separation of the NSAID and the carrier within a kit is within the skill of an artisan versed in the pharmaceutical art in order to increase the shelf life of the NSAID.

Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide the composition disclosed by US '948 and deliver the composition in form of a kit comprising the carrier separate from the drug, motivated by the logic of the cosmetic art that separation of the drug and the carrier may prolong the shelf life of the drug, with reasonable expectation of having a composition comprising NSAID and carrier in form of a kit that has prolonged shelf life.

14. Claims 103 and 111 are rejected under 35 U.S.C. 103(a) as being unpatentable over DE 27 07 537 ('537).

Claim 103 is directed to composition, and the future intended use of the does not impart patentable weight to composition claims.

DE '537 teaches formulations comprising salicylic acid in an amount of 1-3%, and carrier such as ethylene glycol. The formulation comprises gel (thermal insulating material) and a substance that relieve skin irritation.

DE '537 does not teach the kit. The kit is a composition, and the separation of the NSAID and the carrier within a kit is within the skill of an artisan versed in the pharmaceutical art in order to increase the shelf life of the NSAID.

Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide the composition disclosed by DE '537 and deliver the composition in form of a kit comprising the carrier separate from the drug, motivated by the logic of the cosmetic art that separation of the drug and the carrier may prolong the

shelf life of the drug, with reasonable expectation of having a composition comprising NSAID agent and carrier in form of a kit that has prolonged shelf life.

Response to Arguments

15. Applicant's arguments with respect to claims 80, 89, 103, 109, and 111 have been considered but are moot in view of the new ground(s) of rejection. Applicant has not presented any argument in the response filed November 07, 2005 to traverse the rejections previously presented in the final office action.

Response to Amendment

16. The declaration under 37 CFR 1.132 filed January 05, 2006 is insufficient to overcome the rejection of claims 80, 89, 103, 109, and 111 based upon U.S.C. 103 (a) over US '271 and DE '537 as set forth in the last Office action because: it include(s) statements which amount to an affirmation that the claimed subject matter functions as it was intended to function. This is not relevant to the issue of nonobviousness of the claimed subject matter and provides no objective evidence thereof. See MPEP § 716. The declaration refer(s) only to the system described in the above referenced application and not to the individual claims of the application. Thus, there is no showing that the objective evidence of nonobviousness is commensurate in scope with the claims, See MPEP § 716, because the scope of the claims are broad directed to method for treating scar comprising NSAID and carrier and to a kit comprising NSAID and carrier, and the cited prior art as presently applied makes the claims obvious.

In view of the foregoing, when all of the evidence is considered, the totality of the rebuttal evidence of nonobviousness fails to outweigh the evidence of obviousness.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Isis Ghali
Examiner
Art Unit 1615

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